K080600

510(k) Summary

JUN 25 2008

Submitter
UltiMed Inc.
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Date Prepared
2/29/2008

Name of Device

Common Name:	Syringe, Piston
Proprietary Name:	UltiMed UltiCare Safety Syringe (numerous sizes and combinations varying between the smallest 0.5ml x 27G x 5/16" and the largest 3.0ml x 21G x 1½")
Classification Name:	Piston Syringe, Hypodermic Single Lumen Needle, with Sharps Injury Prevention feature
Regulation:	880.5570, 880.5860
Class:	Class II
Product Code:	FMI / FMF / MEG

Predicate Devices
The UltiMed UltiCare Safety Syringe is substantially equivalent in intended use, function and basic composition to the currently marketed Sherwood Medical Co. Monoject Safety Syringe 1cc, 3cc and 12 cc size (K922522).

Device Description
The UltiMed UltiCare Safety Syringe is a standard piston type syringe with permanently attached (uni-body) needle and protective shield. They are sterile, single-use, disposable piston syringes consisting of a syringe barrel, plunger rod with gasket, permanently attached hypodermic single lumen needle, needle cap, and protective shield. The UltiMed UltiCare Safety Syringes are non-toxic and non-pyrogenic, and will be available in a variety of combinations of syringe sizes (0.5 to 3.0 ml (cc)), needle sizes (27 to 21 gauge), and needle lengths (5/16" to 1½"). The protective shield is made of clear plastic and is furnished in a retracted position with the needle cap over the needle. When the needle cap is removed, medication can be drawn and injected in the conventional manner. After the injection, the protective shield is engaged by sliding it away from the finger grip to an extended position over the needle and then applying a turning or rotating motion to lock the shield in place.

Intended Use
UltiMed UltiCare Safety Syringe is intended to inject fluid into, or withdraw fluid from the body. The safety shield aids in the prevention of needle stick injuries.

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Technological Characteristics
The UltiMed UltiCare Safety Syringe has similar technological characteristics to the currently marketed predicate device listed above. The UltiMed UltiCare Safety Syringe meets the following device specific standards:

ISO 7864	(1993)	Sterile Hypodermic Needles for Single Use
ISO 7886-1	(1993)	Sterile Hypodermic Syringes for Single Use
ISO 8537	(1991)	Sterile single-use syringes, with or without needle, for insulin
ISO 9626	(1991)	Stainless Steel Needle Tubing for Manufacture of Medical Devices
ISO 10993 – 1	(2003)	Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing
ISO 10993 – 4	(2002)	Biological Evaluation of Medical Devices: Part 4: Selections of tests for interactions with blood
ISO 10993 – 5	(1999)	Biological Evaluation of Medical Devices: Part 5: Tests for in vitro cytotoxicity
ISO 10993 – 7	(1995)	Biological Evaluation of Medical Devices: Part 7: Ethylene oxide sterilization residuals
ISO 10993 – 10	(2002)	Biological Evaluation of Medical Devices: Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993 – 11	(2006)	Biological Evaluation of Medical Devices: Part 11: Tests for systemic toxicity
ISO 11607-1	(2006)	Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

Performance Data (non-clinical or clinical)
The UltiMed UltiCare Safety Syringe is substantially equivalent to the predicate device based on the descriptive data, compliance with standards, simulated clinical use study, and indications for use.

Conclusion
The technological characteristics and performance data for the UltiMed UltiCare Safety Syringe demonstrates it is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2008

UltiMed, Incorporated
C/O Ms. Carole Stamp
Senior Principal Regulatory and Quality Advisor
Regulatory and Clinical Research Institute, Incorporated
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416-1334

Re: K080600
Trade/Device Name: UltiMed UltiCare Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: June 11, 2008
Received: June 17, 2008

Dear Ms. Stamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

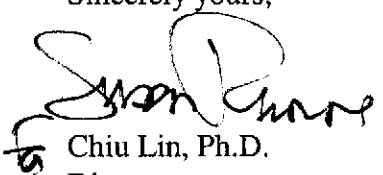
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: Not yet assigned

Device Name: UltiMed UltiCare Safety Syringe

Indications For Use: UltiMed UltiCare Safety Syringe is intended to inject fluid into, or withdraw fluid from the body. The safety shield aids in the prevention of needle stick injuries.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(21 CFR 801.Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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